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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,035	10/15/2003	Earl F. Albone	6750-214-999	9476
20583	7590	01/11/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			GODDARD, LAURA B	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 01/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/687,035

Applicant(s)

ALBONE ET AL.

Examiner

Laura B. Goddard, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-119 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, 28-46, 49-77, 103-112, 116, 118, and 119, drawn to an isolated antibody that preferentially binds cell-associated CA 125/O772P polypeptide relative to shed CA 125/O772P polypeptide, a pharmaceutical composition comprising said antibody, kit, a hybridoma that secretes said antibody, and said antibody conjugated to a cytotoxic agent, classified in class 538, subclass 387.1.
- II. Claims 27, 117, drawn to a monoclonal antibody that competes with the binding of the monoclonal antibody of claim 26 or claim 116, classified in class 530, subclass 378.1.

**Additionally, Applicants must elect a single monoclonal antibody that the claimed monoclonal antibody competes with [4E7, 7A11, 7C6, 7F10, 7G10, 7H1, 8A1, 8B5, 8C3, 8E3, 8G9, 15C9, 16C7, 16H9, 117.1, 325.1, 368.1, 446.1, 501.1, 621.1, 633.1, 654.1, 725.1, or 776.1] as each antibody is a structurally and functionally distinct invention.**

- III. Claim 47, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence that encodes a variable chain region of an antibody, classified in class 536, subclass 23.1.

**Additionally, Applicants must elect a single nucleic acid sequence SEQ ID NO [SEQ ID NOs: 27, 29, 31, 33, 54, 56, 28, 30, 32, 34, 53, or 55] as each sequence presents a structurally and functionally *distinct* invention not a species.**

IV. Claim 48, drawn to an isolated nucleic acid molecule, classified in class 536, subclass 23.1.

**Additionally, Applicants must elect a single nucleic acid sequence SEQ ID NO [SEQ ID NOs: 35, 36, 37, 38, 39, 40, 41, 42, 52, 57, 58, or 59] as each sequence presents a structurally and functionally *distinct* invention not a species.**

V. Claims 78-90, 113-115, drawn to a method for ameliorating a symptom of a CA 125/O772P-related disorder comprising administering to a subject an antibody that preferentially binds cell-associated CA 125/O772P relative to shed CA 125/O772P, classified in class 514, subclass 2.

VI. Claims 91-102, drawn to a method to assist in identifying an antibody that preferentially binds cell-associated CA 125/O772P polypeptide, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Groups III and IV are related to the antibody of Group I by virtue of the fact that the DNA codes for the antibody protein. The DNA molecule has utility for

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the recombinant production of the protein in a host cell. Although the DNA and the antibody are related, since the DNA encodes the specifically claimed antibody, they are distinct inventions because the antibody product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups III, IV and I together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups III, IV and I have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed antibodies as explained above: furthermore, a search of the nucleic acid molecules of Groups III and IV would require an oligonucleotide search,

which is not likely to result in relevant art with respect to the antibody of Group I. As such, it would be burdensome to search the inventions of Groups III, IV and I.

The polynucleotides of Groups III and IV are distinct inventions as they encompass different structures and functions. The antibodies of Groups I and II are distinct inventions as they encompass antibodies of different structure and function.

The polynucleotides of Groups III and IV do not encode the antibody of Group II. The polynucleotide of Groups III and IV and the antibody of Group II are patentably distinct for the following reasons: The antibody of Group II includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibody of Group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Groups III and IV will not encode an antibody of Group II, and the antibody of Group II cannot be encoded by a polynucleotide of Groups III and IV. Therefore, the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups II, III and IV would impose a serious

search burden since a search of the polynucleotides of Groups II and IV would not be used to determine the patentability of any antibody of Group II, and vice-versa.

Inventions I, II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Groups I and II can be used in affinity chromatography or to produce anti-idiotypic antibodies.

The inventions of Groups V and VI are materially distinct methods which differ at least in objectives, method steps and reagents. For example, Group V is drawn to a method of ameliorating a symptom of a CA 125/O772P-related disorder comprising administering an antibody to a subject. Group VI is drawn to the different objective of a method to assist in identifying an antibody. Each of the groups employs chemically distinct reagents to accomplish different objectives that comprise different method steps. Searching all of the groups with all of the different objectives, method steps, and reagents would invoke a high burden of search.

The polynucleotides of Groups III and IV are not used in the methods of Groups V and VI. The antibody of Groups I and II are not used in the method of Group VI.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any other Group, and because some

Groups have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

## **SPECIES ELECTION**

### **Species Election for Group I**

**Applicant is required to elect a species from A and B below:**

**A.** This application contains claims directed to the following patentably distinct, structurally and functionally different **antibody** and related **hybridoma** species of the claimed invention: **4E7, 7A11, 7C6, 7F10, 7G10, 7H1, 8A1, 8B5, 8C3, 8E3, 8G9, 15C9, 16C7, 16H9, 117.1, 325.1, 368.1, 446.1, 501.1, 621.1, 633.1, 654.1, 725.1, or 776.1** (claims 26, 28, 116, 118).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

**Additionally, Applicant is required to elect the heavy and light chain variable regions that correspond to the elected antibody species from A:**

**B.** This application contains claims directed to the following patentably distinct, structurally and functionally different **antibody light and heavy variable chain** species of the claimed invention:



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(a) **light chain SEQ ID NO: 27; heavy chain SEQ ID NO:28** (claims 29, 35, 41)

(b) **light chain SEQ ID NO:29; heavy chain SEQ ID NO:30** (claims 30, 36, 42)

(c) **light chain SEQ ID NO:31; heavy chain SEQ ID NO:32** (claims 31, 37, 43)

(d) **light chain SEQ ID NO:33; heavy chain SEQ ID NO:34** (claims 32, 38, 44)

(e) **light chain SEQ ID NO:54; heavy chain SEQ ID NO:53** (claims 33, 39, 45)

or

(e) **light chain SEQ ID NO:56; heavy chain SEQ ID NO:55** (claims 34, 40, 46)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

#### **Species Election for Group V**

C. This application contains claims directed to the following patentably distinct, structurally and functionally different **antibody** species of the claimed invention: **4E7, 7A11, 7C6, 7F10, 7G10, 7H1, 8A1, 8B5, 8C3, 8E3, 8G9, 15C9, 16C7, 16H9, 117.1, 325.1, 368.1, 446.1, 501.1, 621.1, 633.1, 654.1, 725.1, or 776.1** (claim 90).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 78 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final

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rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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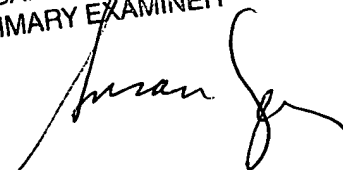
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.  
Examiner  
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SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Susan', followed by a large, stylized flourish or loop.